Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 04-15-2011

Submission # 10

The following request has been:

- ○ Approved
- ☒ Denied

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Tuesday, March 15, 2011 2:38 PM
To: Gennrich, Jane - Medicaid
Subject: FW: Norditropin Flexpro clinical submission for Idaho P&T
Attachments: Growth Hormone Norditropin Flexpro clinical submission Idaho Medicaid 04-15-11mtg.doc; Norditropin Prescriber Info.pdf; Norditropin Patient Information.pdf

Tami Eide, Pharm.D., BCPS
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From: KYBA (Kaysen Bala) [mailto:kyba@novonordisk.com]
Sent: Tuesday, March 15, 2011 12:16 PM
To: Eide, Tamara J. - Medicaid
Cc: CDBB (Chris Dobberpuhl)
Subject: Norditropin Flexpro clinical submission for Idaho P&T

Dear Dr. Eide,

I am writing to you in regards to the upcoming Idaho P&T committee meeting on April 15th, 2011.

On behalf of Novo Nordisk Inc., I would like to request to speak at the P&T committee's meeting to present clinical information on the growth hormone Norditropin® Flexpro®. In accordance to the Idaho P&T committee guidelines, I have attached a clinical submission document for your review. Also attached are the Norditropin® prescribing and patient information documents.

Kindly let me know if you require more information. Thank you.

Best Regards,
Kaysen

Kaysen Bala, Pharm.D.
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March 15th, 2011

Dear Idaho Pharmacy and Therapeutics Committee:

Enclosed, you will find new clinical information on the recently FDA approved growth hormone delivery device, the Norditropin Flexpro®. Also, we would like to share with you some important information highlighting the services Novo Nordisk, Inc. offers. .

1. NORDITROPIN® (somatropin [rDNA origin] injection) DELIVERY DEVICES
Norditropin® Flexpro® - Approved in March 2010, FlexPro® offers enhanced features that support dosing accuracy, such as an easy-to-push dose button and an end-of-dose signal when the entire dose has left the pen.

Summary of key features of Norditropin® FlexPro®:

- Pre-loaded: No mixing, loading or changes of cartridges necessary.
- Ergonomic design
- Easy to read numbers- black on white background
- Different dialing sounds depending on the direction; can potentially avoid dosing errors
- End-of-dose click which indicates that the medication has left the pen
- Small dosing increments: The FlexPro® 5 mg/1.5 mL pen has a dosing increment of 0.025 mg. Physicians have greater flexibility in selecting an optimal dose based on the patient's weight, thus potentially reducing product wastage and generating cost savings[2].
- Storage Flexibility: After initial injection, FlexPro® 5 mg and 10 mg pens can be stored at room temperature (up to 77F) for 3 weeks or in the refrigerator (36-46F) for 4 weeks. This is convenient when patients have to travel with their medication and it can also reduce product wastage if they forget to return the pens back into the refrigerator after use. FlexPro® 15 mg must be refrigerated at all times while in use. All FlexPro® pens must be refrigerated prior to initial use.
- Overfill: FlexPro® has demonstrated overfill to optimize the deliverable doses in each pen and helping to ensure patients receive the full labeled volume in each pen[1].

Fuchs et al evaluated the usability and acceptability of Norditropin® FlexPro® 10 mg pen for the administration of growth hormone in pediatric patients with GH deficiency. This open-label, uncontrolled study included 70 patients between the ages of 10 to <18 years, who completed a 21-item questionnaire on the acceptability and usability of the device. All of the patients reported that learning to use the FlexPro® pen device was very easy or quite easy. FlexPro® pen was reported by 90% of the patients (n=63) to be a lot better in term of the stability of the device as compared to their currently used device. Overall, 45 patients (64%) preferred FlexPro® over the current one, 14 patients were uncertain and 11 patients preferred their current device over FlexPro® pen.

2. FDA APPROVED INDICATIONS

Norditropin® has received FDA approval for five (5) indications: Pediatric and Adult Growth Hormone Deficiency, the treatment of children with short stature associated with Noonan Syndrome, Turner Syndrome and in children born Small for Gestational Age (SGA) with no catch-up growth by age 2 to 4 years. Norditropin® is the only growth hormone FDA approved to treat short stature associated with Noonan syndrome.

3. NORDICARE® SUPPORT

Novo Nordisk offers patients, caregivers, and institutions support services through the NordiCare® program. NordiCare® is administered by nurses, case managers, and reimbursement specialists whose services are provided free of charge by Novo Nordisk Inc.

NordiCare® supports eligible patients by providing a comprehensive starter kit with training materials in English and Spanish, initial supplies of growth hormone to eligible patients at no cost upon physician request (JumpStart™), and product training at a time and place convenient to the patient. Real-time support is available for Spanish-speaking patients, and live translation services are available for a broad array of languages. NordiCare® support extends for as long as a patient remains on Norditropin®.

In addition, NordiCare® also screens and enrolls eligible patients who do not qualify for state Medicaid coverage in the Patient Access Program.

Please see important safety information on pages 4-6.

On behalf of Novo Nordisk Inc., I would like to thank you for your time and request the committee's consideration to maintain Norditropin Flexpro® on the Idaho preferred drug list.

Respectfully yours,

Kaysen Bala, Pharm.D.
Growth Hormone Disorder Medical Scientific Liaison
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Norditropin® Indications and Usage

Norditropin® (somatropin [rDNA origin] injection) is indicated for the treatment of children with growth failure due to inadequate secretion of endogenous growth hormone, the treatment of children with short stature associated with Noonan syndrome or Turner syndrome, the treatment of children with short stature born small for gestational age (SGA) with no catch-up growth by age 2-4 years, and for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD) who meet either of the following two criteria: 1. Adult Onset: Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or 2. Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Important Safety Information

Somatropin should not be used to treat patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure as increased mortality may occur.

Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment. There have been reports of sudden death when somatropin was used in such patients. Norditropin® is not indicated for the treatment of patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

Somatropin should not be used or should be discontinued with any evidence of active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin. Somatropin should be discontinued if there is evidence of recurrent activity. Patients with preexisting tumors or GHD secondary to an intracranial lesion should be monitored routinely for progression or recurrence. In childhood cancer survivors, an increased risk of a second neoplasm, particularly meningiomas in patients treated with radiation to the head for their first neoplasm, has been reported in patients treated with somatropin.

Somatropin should not be used in patients with active proliferative or severe non-proliferative diabetic retinopathy, for growth promotion in pediatric patients with closed epiphyses, or in patients with known hypersensitivity to somatropin or any of its excipients.

Somatropin may decrease insulin sensitivity particularly at higher doses in susceptible patients. Glucose levels should be monitored periodically, including close monitoring of patients with preexisting diabetes or glucose intolerance. Doses of anti-hyperglycemic drugs (insulin or oral agents) may require adjustment for patients with diabetes on somatropin therapy.

Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea and/or vomiting, usually occurring within the first eight (8) weeks after initiation of somatropin therapy, has been reported in a small number of patients. In all reported cases, rapid resolution has occurred after therapy cessation or a reduction of dose. Funduscopic examination should be performed routinely before and during somatropin therapy. If papilledema is observed, somatropin treatment should be discontinued.

Fluid retention during somatropin replacement therapy in adults may frequently occur. Clinical manifestations of fluid retention are usually transient and dose dependent.

In patients with GHD, central (secondary) hypothyroidism may first become evident or worsen during somatropin treatment. Periodic thyroid function tests are recommended and thyroid hormone replacement therapy should be initiated or adjusted as needed.

Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders (including GHD and Turner syndrome) or with rapid growth. Onset of a limp or complaints of hip or knee pain in somatropin patients should be carefully evaluated. Rapid growth may also result in progression of preexisting scoliosis. Patients with a history of scoliosis or skeletal abnormalities, which may be present in untreated Noonan, Turner or Prader-Willi syndrome, should be monitored.

Patients with Turner Syndrome should be evaluated carefully for otitis media and other ear disorders since these patients have an increased risk of ear and hearing disorders. Somatropin treatment may increase the occurrence of otitis media in patients with Turner syndrome. Somatropin may also increase the risk of IH in Turner patients. In addition, patients with Turner syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm/dissection, hypertension) as these patients are also at risk for these conditions.

Congenital heart disease is an inherent component of Noonan syndrome. Though a clinical study in Noonan syndrome reported no evidence of somatropin-induced ventricular hypertrophy or exacerbation of preexisting ventricular hypertrophy (as judged by echocardiography), the safety of Norditropin® in children with Noonan syndrome and significant cardiac disease is not known.

Other somatropin-related adverse reactions include injection site reactions/rashes, lipoatrophy and headaches. Subcutaneous injection of somatropin at the same site repeatedly may result in tissue atrophy and can be avoided by rotating the injection site.

Somatropin inhibits 11ß-hydroxysteroid dehydrogenase type 1 (11ßHSD-1) in adipose/hepatic tissue, and may significantly impact the metabolism of cortisol and cortisone. In patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked requiring glucocorticoid replacement therapy. In addition, patients treated with glucocorticoid replacement therapy, especially with cortisone acetate and prednisone, for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses.

Careful monitoring is advisable when somatropin is administered in combination with other drugs known to be metabolized by CP450 liver enzymes (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine) as limited published data suggest somatropin may alter clearance of these compounds.

In adult women on oral estrogen replacement, a larger dose of somatropin may be required to achieve the defined treatment goal.

The safety and effectiveness of Norditropin® in patients age 65 years and older has not been evaluated in clinical studies. Elderly patients may be more sensitive to the actions of somatropin and may be more prone to develop adverse reactions.

References: 1. Data on file. PDS290 Norditropin® FlexPro® Overfill evaluation. Princeton, NJ: Novo Nordisk Inc.; 2009 **2.** Bazalo GR, Joshi AV, Germak J. Comparison of human growth hormone products' cost inpediatric and adult patients: a budgetary impact model. *Managed Care*. 2007;16(9):45-51. **3.** Dow Jones 2010 Sustainability Index. http://sustainability-index.com/djsi_protected/djsi_world/components/SAM_DJSIWorld_Components.pdf. Accessed July 14, 2010. **4.** World's Most Ethical Companies. *Ethisphere magazine. http://ethisphere.com/wme2010. Accessed May 3, 2010.* **5.** Global 100 Most Sustainable Corporations in the World. http://global100.org/list/global-100-2010-review-results.html. Accessed May 3, 2010